

REMARKS

The Official Action dated October 23, 2008 and the references cited therein have been carefully reviewed. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

Applicants note that the Examiner has indicated that all previously raised objections and rejections to the claims have been overcome. Claims 1, 2, 5-8, 10-14, 16-20 and 22-27 are currently under consideration. Further, the Examiner has indicated that claim 14 is directed to allowable subject matter provided it is rewritten in independent form to include all the limitations of the base claim and any intervening claim.

Claims 1, 5, 8, 16, 17, 22, 23, 27 have been objected for containing certain minor informalities. These errors have been rectified in accordance with the present amendment, thereby rendering this objection moot.

At page 5 of the Official Action, the Examiner has rejected claims 1, 2, 5-8, 10, 11, and 27 under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. These claims have been amended in accordance with the present amendment to remove any perceived lack of clarity.

The Examiner has rejected claims 1, 2, 8, 11, 12, 13, 16-20, and 22-27 under 35 U.S.C. §102 as allegedly anticipated by Sorlie et al. (2001).

The foregoing objections and rejections constitute all of the grounds set forth in the October 23, 2008 Official Action for refusing the present application. Each of these objections and rejections is traversed for the reasons set forth below.

CLAIM AMENDMENTS

Applicants do not concur with the positions taken by the Examiner but are making the following amendments for the sole purpose of expediting prosecution of the present application. Applicants reserve the right to file one or more continuing applications under 35 U.S.C. §120 on the subject matter cancelled in accordance with this amendment.

Claim 1 has been amended to remove the grounds of objection raised by the Examiner and to also include the features of claim 8. Support for this amendment can be found in cancelled claim 8.

Support for the phrase "standard expression signature profile of known prognoses" can be found at least at Page 10 of the published specification.

Support for the recitation of "high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6 or low NPI (NPI value < the cut-off value of 3.8 to 4.6)" can be found at Page 4 and at Page 10 of the published specification.

Claim 4 has been amended to correct a typographical error.

Claims 12 and 16 have been amended to recite a prognostic set of genes including specific sequences as indicated.

Claim 14 has been amended such that it is now in independent form and recites all of the features of previous claim 12. Applicants submit that the foregoing amendment to claim 14 places this claim in condition for allowance.

Claims 22 and 23 have been amended to correct typographical errors and to recite a prognostic set of specific genes as indicated.

New dependent claim 28 reciting "NPI value" has been introduced and finds support in the specification at page 40 and in Figure 2.

Previous claims 2, 8, 10, 13, 17 and 24 have been cancelled thereby rendering any objection or rejection of

these claims moot.

Applicants respectfully submit that the amendments are fully supported by the published specification and do not include any added subject matter.

**THE METES AND BOUNDS OF CLAIMS 1, 2, 5-8, 10, 11 AND 27 ARE
CLEAR TO ONE OF ORDINARY SKILL IN THE ART**

The Examiner has rejected the aforementioned claims as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

It is the Examiner's position that there is insufficient antecedent basis for the phrase "the expression profile under test" in claim 1. The claim has been amended to remove the phrase "under test", thereby removing this ground of rejection. Claim 1 is also allegedly unclear for the recitation of "the prognostic set of nucleic acid products", (also applicable to dependent previous claims 2, 5-8, 10 and 11). Claim 1 has been amended to recite "the expression profile of said patient" and "prognostic set of genes". It is respectfully submitted that proper antecedent basis is present for these recitations and thus, this ground of rejection has been overcome.

The Examiner contends that claim 1 and dependent claims 2, 5-8 and 10-11 lack clarity because of the reference to "poorer prognosis". The Examiner has also asserted that it is not clear what is to be compared with the previously determined standard expression signature in claim 1. In response, Applicants have amended claim 1 to clearly recite how the prognosis is determined by relating gene expression to high and low NPI as defined. It is respectfully submitted that the foregoing amendment removes any perceived lack of clarity from the claim.

The Examiner has also rejected claim 1 and dependent claims 2, 5-8 and 10-11 because there is no antecedent basis

for "the tumour sample" in the claim. Claim 1 has been amended to recite "breast tumour sample" and accordingly, this objection has been obviated.

Claims 11 and 27 have been rejected as there is allegedly insufficient antecedent basis for the phrase "the expression levels of the prognostic set" in these claims.

The claims have been amended to recite "expression profiles of the prognostic set of genes", thereby removing this ground of rejection.

In view of the foregoing claim amendments, Applicants submit that the metes and bounds of the claims would be clear to one of the skill in the art. Nothing more is required under 35 U.S.C. §112, second paragraph. Accordingly, Applicants request that the rejection of claims 1, 2, 5-8, 10, 11, and 27 for alleged indefiniteness be withdrawn.

**CLAIMS 1, 2, 8, 11, 12, 13, 16-20, AND 22-27 AS AMENDED ARE
NOVEL OVER THE DISCLOSURE IN SORLIE ET AL.**

In order for a reference to anticipate a claim, each and every element must be identically disclosed therein. Applicants respectfully submit that Sorlie et al. do not disclose methods and apparatus that are identical to those instantly claimed.

It is noted that the Examiner acknowledges at Page 11 of the Official Action that Sorlie et al. do not use the term NPI. The Examiner also commented that the instant claims do not include the limits of an NPI expression profile. Claim 1 has been amended to clearly define the classification method relating the expression profile of the prognostic set of genes to classification into high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6) or low NPI (NPI value < the cut-off value of 3.8 to 4.6). Applicants submit that this feature is not disclosed in Sorlie et al.

The Examiner further asserts that claims 1 and 2 "do not require the obtained expression of nucleic products to include any nucleic acids represented by SEQ ID Nos: 1-13; rather the obtained expression profile of nucleic acid products can be any nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID Nos: 1-13".

Claim 1 as amended recites the prognostic set of genes comprising SEQ ID NO: 1-13 for comparison. It is submitted that contrary to the Examiner's assertion, Sorlie et al. do not suggest the selection of these particular sequences for the prognostic set of genes in the method disclosed in that reference.

Based on the discussion above, it is respectfully submitted that claim 1 as amended, and claims dependent therefrom are not anticipated by Sorlie et al.

Claims 12, 16 and 22-23 have been amended to require the presence of a prognostic set of genes including SEQ ID Nos: 1-13 as indicated. It is respectfully submitted that the aforementioned claims are not anticipated by Sorlie et al. who do not suggest the selection of these sequences for the prognostic set of genes.

Inasmuch as the claims as amended recite features that are not disclosed in Sorlie et al., it is respectfully requested that the rejection of claims 1, 2, 8, 11, 12, 13, 16-20 and 22-27 for alleged lack of novelty be withdrawn.

CONCLUSION

In view of the remarks presented herewith, it is respectfully urged that the objections and rejections set forth in the October 23, 2008 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the

Examiner is requested to telephone the undersigned at the phone number given below.

Respectfully submitted,
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